

**SECOND  
INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

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of

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**Complete if Known**

Application Number 10/648,282

**Filing Date** August 27, 2003

**First Named Inventor** Faison Jr, Gene G. et. al.

Examiner Name	Not Yet Assigned
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Attorney Docket Number 033018-137

APR 02 2004

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## U.S. PATENT DOCUMENTS

## FOREIGN PATENT DOCUMENTS

## NON-PATENT LITERATURE DOCUMENTS

Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.

Examiner Signature	/Amadeus Lopez/	Date Considered	02/13/2007
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**\*EXAMINER:** Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

THIRD  
INFORMATION DISCLOSURE  
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Sheet 1 of

Complete If Known	
<b>Application Number</b>	10/648,282
<b>Filing Date</b>	August 27, 2003
<b>First Named Inventor</b>	Faison Jr, Gene G. et al.
<b>Examiner Name</b>	Not Yet Assigned
<b>Attorney Docket Number</b>	033018-137

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## U.S. PATENT DOCUMENTS

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AL	Notification of Transmittal of the International Search Report and the Written Opinion of the International Searching Authority, or the Declaration dated December 21, 2004 for PCT/US2004/026613

Examiner Signature	/Amadeus Lopez/	Date Considered	02/13/2007
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Substitute for forms 1449A/PTO & 1449B/PTO		ATTORNEY'S DKT NO. 033018-137	APPLICATION NO. 10/648,282
FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT Gene G. FAISON Jr. et al.	
		FILING DATE August 27, 2003	GROUP Unassigned

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PATENT & TRADEMARK OFFICE

U.S. PATENT DOCUMENTS				
Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
AL	2,896,856	A	Kravits	07/1959
	3,084,698	A	Smith	04/1963
	3,157,179	A	Paullus et al.	11/1964
	3,162,324	A	Houser	12/1964
	3,431,393	A	Katsuda	03/1969
	3,486,663	A	Humphrey	12/1969
	3,658,059	A	Steil	04/1972
	3,716,416	A	Adlhart et al.	02/1973
	3,750,961	A	Franz	08/1973
	3,847,304	A	Cohen	11/1974
	3,859,398	A	Havstad	01/1975
	3,902,635	A	Jinotti	09/1975
	3,903,883	A	Pecina et al.	09/1975
	3,904,083	A	Little	09/1975
	3,967,001	A	Almaula et al.	06/1976
	3,987,941	A	Blessing	10/1976
	3,993,246	A	Erb et al.	11/1976
	3,995,37	A	O'Keefe	12/1976
	4,042,153	A	Callahan et al.	08/1977
	4,060,082	A	Lindberg et al.	11/1977
	4,077,542	A	Petterson	03/1978
	4,161,282	A	Erb et al.	07/1979
	4,162,501	A	Mitchell et al.	07/1979
	4,215,708	A	Bron	08/1980
	4,231,492	A	Rios	11/1980
	4,258,073	A	Payne	03/1981
	4,259,409	A	Arnold	03/1981
	4,261,356	A	Turner et al.	04/1981
	4,289,003	A	Yang	09/1981
	4,291,838	A	Williams	09/1981
	4,303,083	A	Burruss, Jr.	12/1981
	4,383,171	A	Sinha et al.	05/1983
	4,391,308	A	Steiner	07/1983
	4,395,303	A	Weir	07/1983
	4,433,797	A	Galia	02/1984
	4,471,892	A	Coleman	09/1984
	4,512,341	A	Lester	04/1985
	4,575,609	A	Fassel et al.	03/1986
	4,627,432	A	Newell et al.	12/1986

Substitute for forms 1449A/PTO & 1449B/PTO		ATTORNEY'S DKT No. 033018-137	APPLICATION NO. 10/648,282
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**FIRST INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

U.S. PATENT DOCUMENTS				
AL	Patent No.	Assignee	Examiner	Issue Date
	4,649,911	A	Knight et al.	03/1987
	4,682,010	A	Drapeau et al.	07/1987
	4,695,625	A	Macdonald	09/1987
	4,700,657	A	Butland	10/1987
	4,730,111	A	Vestal et al.	03/1988
	4,735,217	A	Gerth et al.	04/1988
	4,744,932	A	Browne	05/1988
	4,749,778	A	Fukuzawa et al.	06/1988
	4,762,995	A	Browner et al.	08/1988
	4,764,660	A	Swiatosz	08/1988
	4,776,515	A	Michalchik	10/1988
	4,790,305	A	Zoltan et al.	12/1988
	4,811,731	A	Newell et al.	03/1989
	4,819,625	A	Howe	04/1989
	4,819,834	A	Thiel	04/1989
	4,829,996	A	Noakes et al.	05/1989
	4,837,260	A	Sato et al.	06/1989
	4,848,374	A	Chard et al.	07/1989
	4,871,115	A	Hessey	10/1989
	4,871,623	A	Hoopman et al.	10/1989
	4,877,989	A	Drews et al.	10/1989
	4,911,157	A	Miller	03/1990
	4,922,901	A	Brooks et al.	05/1990
	4,926,852	A	Zoltan et al.	05/1990
	4,935,624	A	Henion et al.	06/1990
	4,941,483	A	Ridings et al.	07/1990
	4,947,875	A	Brooks et al.	08/1990
	4,974,754	A	Wirz	12/1990
	4,982,097	A	Slivon et al.	01/1991
	4,992,206	A	Waldron	02/1991
	5,021,802	A	Allred	06/1991
	5,044,565	A	Alexander	09/1991
	5,056,511	A	Ronge	10/1991
	5,060,671	A	Counts et al.	10/1991
	5,063,921	A	Howe	11/1991
	5,096,092	A	Devine	03/1992
	5,125,441	A	Mette	06/1992
	5,133,343	A	Johnson, IV et al.	07/1992
	5,134,993	A	van der Linden et al.	08/1992
	5,135,009	A	Muller et al.	08/1992
	5,144,962	A	Counts et al.	09/1992

Substitute for forms 1449A/PTO & 1449B/PTO		ATTORNEY'S DKT No. 033018-137	APPLICATION NO. 10/648,282
		APPLICANT Gene G. FAISON Jr. et al.	
		FILING DATE August 27, 2003	GROUP Unassigned

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DEC 05 2003  
U.S. PATENT & TRADEMARK OFFICE

**FIRST INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

U.S. PATENT DOCUMENTS			
TRADEMARK	5,151,827	A	Ven et al.
	5,178,305	A	Keller
	5,184,776	A	Minier
	5,217,004	A	Blasnik et al.
	5,226,441	A	Dunmire et al.
	5,228,444	A	Burch
	5,230,445	A	Rusnak
	5,231,983	A	Matson et al.
	5,259,370	A	Howe
	5,290,540	A	Prince et al.
	5,298,744	A	Mimura et al.
	5,299,565	A	Brown
	5,322,057	A	Raabe et al.
	5,327,915	A	Porenski et al.
	5,342,180	A	Daoud
	5,342,645	A	Eisele et al.
	5,349,946	A	McComb
	5,395,445	A	Bohanan
	5,421,489	A	Holzner, Sr. et al.
	5,462,597	A	Jubran
	5,474,059	A	Cooper
	5,509,557	A	Jimarez et al.
	5,515,842	A	Ramseyer et al.
	5,522,385	A	Lloyd et al.
	5,556,964	A	Hofstraat et al.
	5,559,923	A	Robelen
	5,564,442	A	MacDonald et al.
	5,565,677	A	Wexler
	5,575,929	A	Yu et al.
	5,585,045	A	Heinonen et al.
	5,617,844	A	King
	5,642,728	A	Andersson et al.
	5,674,860	A	Carling et al.
	5,682,874	A	Grabenkort et al.
	5,706,389	A	Pohler
	5,730,158	A	Collins et al.
	5,743,251	A	Howell et al.
	5,756,995	A	Maswadeh et al.
	5,765,724	A	Amberg et al.
	5,823,178	A	Lloyd et al.
	5,839,430	A	Cama

Substitute for forms 1449A/PTO &amp; 1449B/PTO

ATTORNEY'S DKT NO.  
033018-137APPLICATION NO.  
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UnassignedFIRST INFORMATION DISCLOSURE  
STATEMENT BY APPLICANTOIE  
DEC 05 2003  
U.S. PATENT DOCUMENTS

TRADEMARK	NUMBER	NAME	DATE
	5,855,202	A Andrade	01/1999
	5,856,671	A Henion et al.	01/1999
	5,863,652	A Matsumura et al.	01/1999
	5,869,133	A Anthony et al.	02/1999
	5,870,524	A Swiatosz	02/1999
	5,872,010	A Karger et al.	02/1999
	5,878,752	A Adams et al.	03/1999
	5,881,714	A Yokoi et al.	03/1999
	5,906,202	A Schuster et al.	05/1999
	5,914,122	A Otterbeck et al.	06/1999
	5,932,249	A Gruber et al.	08/1999
	5,932,315	A Lum et al.	08/1999
	5,934,272	A Lloyd et al.	08/1999
	5,934,273	A Andersson et al.	08/1999
	5,944,025	A Cook et al.	08/1999
	5,954,979	A Counts et al.	09/1999
	5,957,124	A Lloyd et al.	09/1999
	5,970,973	A Gonda et al.	10/1999
	5,970,974	A Van Der Linden et al.	10/1999
	5,978,548	A Holmstrand et al.	11/1999
	5,993,633	A Smith et al.	11/1999
	6,014,970	A Ivri et al.	01/2000
	6,053,176	A Adams et al.	04/2000
	6,054,032	A Haddad et al.	04/2000
	6,069,214	A McCormick et al.	05/2000
	6,069,219	A McCormick et al.	05/2000
	6,070,575	A Gonda et al.	06/2000
	6,071,428	A Granks et al.	06/2000
	6,071,554	A Isomura et al.	06/2000
	6,076,522	A Dwivedi et al.	06/2000
	6,077,543	A Gordon et al.	06/2000
	6,080,721	A Patton	06/2000
	6,085,740	A Ivri et al.	07/2000
	6,085,753	A Gonda et al.	07/2000
	6,089,228	A Smith et al.	07/2000
	6,095,153	A Kessler et al.	08/2000
	6,098,615	A Lloyd et al.	08/2000
	6,098,620	A Lloyd et al.	08/2000
	6,103,270	A Johnson et al.	08/2000
	6,116,516	A Gannan-Calvo	09/2000
	6,116,893	A Peach	09/2000

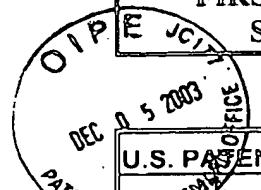


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U.S. PATENT DOCUMENTS				
TRADE FEE	NUMBER	TYPE	NAME	DATE
	6,119,953	A	Ganan-Calvo et al.	09/2000
	6,123,068	A	Lloyd et al.	09/2000
	6,123,936	A	Platz et al.	09/2000
	6,131,567	A	Gonda et al.	10/2000
	6,131,570	A	Schuster et al.	10/2000
	6,136,346	A	Eljamal et al.	10/2000
	6,138,668	A	Patton et al.	10/2000
	6,155,268	A	Takeuchi	12/2000
	6,158,431	A	Poole	12/2000
	6,158,676	A	Hughes	12/2000
	6,159,188	A	Laibovitz et al.	12/2000
	6,164,630	A	Birdsell et al.	12/2000
	6,165,463	A	Platz et al.	12/2000
	6,167,880	B1	Gonda et al.	01/2001
	6,174,469	B1	Ganan-Calvo	01/2001
	6,182,712	B1	Stout et al.	02/2001
	6,187,214	B1	Ganan-Calvo	02/2001
	6,187,344	B1	Eljamal et al.	02/2001
	6,189,453	B1	Lin	02/2001
	6,189,803	B1	Ganan-Calvo	02/2001
	6,192,882	B1	Gonda	02/2001
	6,197,835	B1	Ganan-Calvo	03/2001
	6,205,999	B1	Ivri et al.	03/2001
	6,206,242	B1	Amberg et al.	03/2001
	6,207,135	B1	Rossling et al.	03/2001
	6,233,746	B1	Jewett et al.	05/2001
	6,230,706	B1	Gonda et al.	05/2001
	6,231,851	B1	Platz et al.	05/2001
	6,234,167	B1	Cox et al.	05/2001
	6,234,402	B1	Ganan-Calvo	05/2001
	6,235,177	B1	Borland et al.	05/2001
	6,250,298	B1	Gonda et al.	06/2001
	6,257,233	B1	Burr et al.	07/2001
	6,258,341	B1	Foster et al.	07/2001
	6,263,872	B1	Schuster et al.	07/2001
	6,267,155	B1	Parks et al.	07/2001
	6,275,650	B1	Lambert	08/2001
	6,276,347	B1	Hunt	08/2001
	6,284,525	B1	Mathies et al.	09/2001
	6,288,360	B1	Beste	09/2001
	6,290,685	B1	Insley et al.	09/2001

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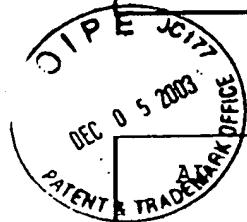


U.S. PATENT DOCUMENTS			
TRADEMARK	6,294,204	B1	Rossling et al.
	6,295,986	B1	Patel et al.
	6,318,361	B1	Sosiak
▼	2001/0032647	A1	Schuster et al.
	6,640,050	B2	Nichols et al.

FOREIGN PATENT DOCUMENTS					
Examiner Initials	Document Number	Kind Code (if known)	Country	Date of Publication (MM-DD-YYYY)	Translation Yes No
AL	354004	A	Belgium	09/1928	
	354094	A	Belgium	09/1928	X
	1036470	B1	Germany	08/1958	X
	0358114	A	EPO	03/1990	
	0642802	A2	EPO	05/1996	
	667979	A	France	10/1929	X
	216121	B	Hungary (Abstract only)	03/1991	
	207457	A	Hungary	04/1993	
	P953409		Hungary (Abstract only)	06/1994	
	168128	B	Hungary (Abstract only)	11/1997	
▼	94/09842	A	WIPO	05/1994	
	98/17131		WIPO	04/1994	

NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
AL	Barry, P.W. et al. "In Vitro Comparison of the Amount of Salbutamol Available for Inhalation From Different Formulations Used with Different Spacer Devices" Eur Respir J 1997; 10:1345-1348.
	Byron, Peter R. Ph.D., Chairman, "Recommendations of the USP Advisory Panel on Aerosols on the USP General Chapters on Aerosols (601) and Uniformity of Dosage Units (905)", Pharmacopeial Forum, vol. 20, No. 3, pp. 7477-7505, May-Jun. 1994 (023).
	Hindle, Michael et al., "High Efficiency Aerosol Production Using the Capillary Aerosol Generator" PharmSci 1998; 1: (1: suppl) S211.
	Hindle, Michael et al., "High Efficiency Fine Particle Generation Using Novel Condensation Technology", Respiratory Drug Delivery VI (eds Dalby, R.N., Byron, P.R. & Farr, S.J.) Interpharm Press, Buffalo Grove, IL 1998 pp. 97-102.
	Hou, Shuguang et al. Solution Stability of Budensonide in Novel Aerosol Formulations Abstract No. 2582, Solid State Physical Pharmacy, Nov. 17, 1998, p. S-307.
	Kousaka, Yasuo et al., "Generation of Aerosol Particles by Boiling of Suspensions", Aerosol Science and Technology, 21:236-240 (1994) (023).
	Moren, Folke "Drug Deposition of Pressurized Inhalation Aerosols I. Influence of Actuator Tube Design" AB Draco (Subsidiary of AB Astra, Sweden) Research and Development Laboratories Pack, S-221 01 Lund (Sweden), International Journal of Pharmaceutics, 1 (1978) 205-212.
▼	Newman, Stephen P. et al. "Deposition of Pressurized Suspension Aerosols Inhaled Through Extension Devices.sup.1-3 "Am Rev Respir Dis 1981; 124:317-320.

Substitute for forms 1449A/PTO & 1449B/PTO	ATTORNEY'S DKT NO. 033018-137	APPLICATION NO. 10/648,282
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	Roth, G. et al. High Performance Liquid Chromatographic Determination of Epimers, Impurities, and Content of the Glucocorticoid Budesonide and Preparation of Primary Standard, Journal of Pharmaceutical Sciences, vol. 69, No. 7, pp. 766-770, Jul. 1980.
AL	Notification of Transmittal of the International Search Report or the Declaration dated Feb. 14, 2003 for PCT/US02/28703.
AL	Written Opinion for PCT/US02/28703 dated Jul. 8, 2003.

Examiner Signature	/Amadeus Lopez/	Date Considered	09/19/2006
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